Disulfiram tablets 200mg

Read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.

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1. What Disulfiram is and what it is used for
Disulfiram is used as a supportive agent in the treatment of alcoholism. When you drink alcohol it is changed in the body into acetaldehyde, disulfiram blocks the enzyme which breaks down acetaldehyde. This leads to an increased level of acetaldehyde in the blood causing unpleasant physical reactions.

Disulfiram is used in the treatment of people with drinking problems. If you are treated with Disulfiram and drink alcohol you will experience unpleasant physical reactions, which may stop you from drinking further alcohol.

2. Before you take

Do not take Disulfiram tablets and tell your doctor if you have:
- an allergy (hypersensitivity) to disulfiram or any of the other ingredients (see section 6)
- severe heart disease or heart failure
- high blood pressure
- severe psychiatric or personality disorder
- had a stroke.
- recently consumed alcohol

Check with your doctor or pharmacist before taking Disulfiram tablets if you have:
- kidney, liver or lung disease
- diabetes
- low blood pressure
- brain damage
- epilepsy.

Taking other medicines
Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. Especially:

- warfarin (reduces blood clotting)
- phenytoin and paraldehyde (to treat epilepsy)
Other precautions
Certain foods, liquid medicines, remedies, tonics, toiletries, perfumes and sprays may contain enough alcohol to cause a disulfiram-alcohol reaction. Caution should also be exercised with low alcohol and “non-alcoholic” or “alcohol-free” beers and wines, if enough is taken they may produce unpleasant reactions.

Pregnancy and breast-feeding
If you are pregnant, planning to become pregnant or are breast-feeding ask your doctor or pharmacist for advice before taking this medicine.
The use of Disulfiram tablets during the first 3 months of pregnancy or breast feeding is not advised and should only be used if directed by your doctor.

Driving and using machines
Disulfiram tablets may cause drowsiness or tiredness (see ‘4. Possible side effects’). If you are affected do not drive or operate machinery.

Sugar intolerance
If you have been told you have an intolerance to some sugars, contact your doctor before taking this medicine, as it contains a type of sugar called lactose.

Alcohol
If you drink alcohol during or within 2 weeks of stopping Disulfiram tablets, or you have been exposed to alcohol from other sources (see ‘Other precautions’) a disulfiram-alcohol reaction may occur. The reaction is unpredictable and symptoms may be severe or life threatening. Symptoms include; flushing of the face and neck, increased body temperature, sweating, feeling or being sick, itchy skin or rash caused by an allergic reaction (pruritis, urticaria) anxiety, dizziness, headache, blurred vision, difficulty breathing, palpitations, rapid breathing,
In severe cases; rapid heart beat, low blood pressure, abnormally slow breathing, chest pain, abnormal heart rhythm, coma or fits may occur.
Rare complications may include; high blood pressure, breathing problems, blood disorders.
If you get some of the symptoms, contact your doctor.
The disulfiram-alcohol reaction can occur within 15 minutes after drinking alcohol and may last several hours.

3. How to take
Always take Disulfiram tablets exactly as your doctor has told you. If you are not sure, check with your doctor or pharmacist. A check up is advised before starting treatment to check you are suitable for treatment.

Treatment with Disulfiram is usually started in a hospital or specialised clinic. It is important that you have not drunk alcohol for at least 24 hours before taking the first dose. Swallow the tablets with water.

Doses:
• Adults and the elderly:
Initially 4 tablets (800mg) on day 1, then 3 tablets (600mg) on day 2, then 2 tablets (400mg) on day 3 and then 1 tablet (200mg) on days 4 and 5. Then ½ to 1 tablet (100mg – 200mg) a day for as long as told by your doctor, but for no longer than six months without review.

If you take more than you should
If you (or someone else) swallow a lot of tablets at the same time, or you think a child may have swallowed any, contact your nearest hospital casualty department or tell your doctor immediately. Signs of an overdose include; feeling or being sick, stomach pain, diarrhoea, drowsiness, mental disorders, tiredness, rapid heart beat, rapid breathing, high body temperature, low blood pressure, loss of muscle control, high blood sugar, changes in the blood (as seen in blood tests). Severe cases may result in coma, fits or death.

If you forget to take the tablets
If you forget to take a dose, and you do not remember it within 12 hours, you should not take it. Do not take two doses the next time.

4. Possible side effects

Like all medicines, Disulfiram tablets can cause side effects, although not everybody gets them.

Tell your doctor if you notice any of the following side effects or notice any other effects not listed:
• depression, paranoia, schizophrenia, mania,
• decreased sexual desire
• drowsiness and fatigue (especially at start of treatment)
• damage/inflammation of peripheral nerves (causing pain and loss of sensation in hands and feet)
• inflammation of the optic nerve
• encephalopathy (brain disease)
• feeling or being sick
• bad breath
• inflammation of the liver (hepatitis), damage to liver cells, liver failure
• allergic skin reactions such as itching and redness.

If you notice any side effects, they get worse, or if you notice any not listed, please tell your doctor or pharmacist.

5. How to store

Keep out of the reach and sight of children.
Store below 25°C in the tightly closed container, protect from light in a dry place.
Do not use Disulfira tablets after the expiry date stated on the label/carton/bottle. The expiry date refers to the last day of that month.
Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Further information

What Disulfiram tablets contain
• The active substance (the ingredient that makes the tablet work) is 200mg of disulfiram.
• The other ingredients are lactose, potato starch, povidone, microcrystalline cellulose, polysorbate 20, tartaric acid, colloidal anhydrous silica, sodium bicarbonate, maize starch and magnesium stearate.

Contents of the pack
Pack sizes are 50 tablets

Marketing Authorisation Holder
Actavis Group PTC ehf. Reykjavikurvegi 76-78, 220 Hafnarfjordur,
Iceland

**Manufacturer**
Kemwell AB, Bjorkgatan 30, 751 82 Uppsala, Sweden

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